AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include new FIGS. 4 and 5. These sheets replace the original sheets including FIGS. 4 and 5.

Attachment: Replacement Sheets FIGS. 4 and 5

REMARKS

The non-Final Office Action dated January 25, 2007 has been received and reviewed. Claims 1, 3, 5-8, 10, 12-15, 17, 19-21 are pending in the subject application. All claims stand rejected. Claims 1, 3, 5, 6, 8, 10, 12, 13, 15, 17, 19 and 20 have been amended herein and claims 2, 4, 9, 11, 16 and 18 have been cancelled. Care has been exercised to introduce no new matter. Reconsideration of the present application in the above amendments and the following remarks is respectfully requested.

Objections

The drawings have been objected to as Figures 4 and 5 are too dark. Applicants have submitted new drawings for Figures 4 and 5 herewith. As such, Applicants request withdrawal of the objection to the drawings.

Rejections based on 35 U.S.C. § 101

Claims 8–14 have been rejected under 35 U.S.C. § 101 as being directed toward a computer program *per se*. Claim 8 has been amended herein to recite, in part, "[a] computer system embodied on one or more *computer storage media* having computer-executable instructions embodied thereon for preventing atypical clinical events related to information identified by DNA testing a person" (emphasis added). It is respectfully submitted that computer storage media is not a computer program *per se*. Rather, as described in the Specification, computer storage media includes media used in the storage of information. *See Detailed Description* at paragraph **[0025]**. When used in the computer system, the computer storage media recited in claim 8 are capable of producing a useful, concrete, and tangible result and, accordingly, is believed to be directed to statutory subject matter. As such, withdrawal of the 35 U.S.C. § 101 rejection of claim 8 is respectfully requested. As claims 9-14 depend, either

directly or indirectly, from independent claim 8, Applicants respectfully request withdrawal of the § 101 rejections of these claims for at least the above-cited reasons.

Rejections based on 35 U.S.C. § 112, first paragraph

Claims 1-21 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In particular, it is the Office's contention that the claims are not enabled because neither the specification nor the prior art teach how to determine the likelihood of a person having a gene variant indicative of an atypical clinical event (a) in the absence of any genetic test result and/or (b) in the absence of a step of determining if a test result value indicates the presence of a polymorphism/variant which is known to be associated with or indicative of an atypical event.

The first paragraph of 35 U.S.C. §112 requires that the written description be sufficient to enable a person skilled in the art to which it pertains to make and use the invention. The courts have interpreted this statutory provision as establishing an enablement requirement that is distinct from written description and best mode.

Case law has made it abundantly clear that an analysis of whether a claim is enabled is based on whether the disclosure contained sufficient information as to enable one skilled in the pertinent art to make and use the invention. MPEP 2164.01. The enablement question can be more specifically asked as whether a person skilled in the art could make and use the invention without undue experimentation.

Applicants submit that independent claims 1 and 15 have been amended to include the step of accessing a data structure to determine if a genetic polymorphism value is known to be associated with one or more atypical events for the clinical agent information. Independent claim 8 has been amended to include a first accessing component for accessing a

data structure of gene variants known to be associated with agents and atypical clinical events. Applicants submit that the amendments to the claims are supported by the specification. In particular, Table 1 is an exemplary data structure of a table containing gene variants and agents and Table 2 is an exemplary data structure containing gene variants, agents and risks. Furthermore, accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information in response to receiving clinical agent information is supported in originally filed claims 1 and 4 and in paragraphs [0050] and [0051] (examples that the likelihood that a person has a gene variant and the associated atypical event in response to receiving clinical agent information). Further support may be found in paragraphs [0040], [0045], [0049] and [0050] of the specification.

Applicants respectfully submit that applying the proper test to the claims shows that the claims are enabled since it would not require "undue experimentation" based on the specification's disclosure to add newly accepted relationships between gene variants and atypical events to the data structure. Applied to this case, the undue experimentation question boils down to whether, based on Applicants disclosure of a data structure containing known associations of gene variants and atypical events, a person skilled in the art would be able to carryout the invention as claimed. Applicants contend that one skilled in the art, (e.g., a computer programmer) using the specification's disclosure of a data structure of gene variants and atypical events would find it a routine matter to add new information to a data structure as it becomes available.

Similarly, independent claims 1 and 15 have been amended to include steps accessing hereditary information for the person if the person does not have a genetic test result value for the gene variant and utilizing the hereditary information for the person to determine the

likelihood the person has the gene variant. Independent claim 8 has been amended to include a second accessing component for accessing hereditary information for the person if the person does not have a genetic test result value for the gene variant and a utilizing component for utilizing the hereditary information for the person to determine the likelihood the person has the gene variant. Support for these amendments may be found in paragraphs [0041], [0050] and [0051]. In particular, rules are disclosed for utilizing the hereditary information for the person to determine the likelihood the person has the gene variant based on whether a person has particular demographic information to satisfy the rule (e.g., because a person is from the Indian subcontinent, they have an increased risk of cytoxicity in response to mercaptopurine).

Applicants respectfully submit that applying the proper test to the claims shows that the claims are enabled since it would not require "undue experimentation" based on the specification's disclosure to write new rules regarding demographic information and gene variants as it comes available. Applicants submit that the adding new rules regarding demographic information and gene variants as it becomes available based on the specification's disclosure of and gene variants is routine for persons skilled in the relevant art (e.g., a computer programmer). Applicants contend that one skilled in the art, using the rules described in the specification for gene variants and atypical events, one of skill in the art would find it a routine matter to add write new rules regarding demographic information and gene variants as the information becomes available.

As such, Applicants submit that amended claims 1, 8 and 15 include such limitations supported by the specification that would enable one of skill in the art to make and use the invention. As such, Applicants request withdrawal of the §112 rejection of these claims.

Rejections based on 35 U.S.C. § 112, second paragraph

Claims 1-21 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, claims 1, 8 and 15 have been rejected as being incomplete for omitting essential elements. Applicants submit that claims 1, 8 and 15 have been amended and request withdrawal of the §112 rejection of these claims.

Claims 2, 9 and 16 have been rejected for use of the phrase "a variation from the risk of the presence of a polymorphism in the general population." Applicants have canceled claims 2, 9 and 16 and as such, Applicants request withdrawal of this rejection.

Claims 4, 11 and 18 have been rejected for reciting a "further comprising step." Claims 4, 11 and 18 have been canceled, and as such, Applicants request withdrawal of this rejection.

Claims 5, 12 and 19 have been rejected for the recitation that hereditary information "is obtained." Claims 5, 12 and 19 have been amended to indicate that these further define limitations of claims 1, 8 and 15. As such, Applicants request withdrawal of the rejection of claims 5, 12 and 19.

Claim 15 has been rejected for the use of the phrase "comprising the steps of" in the preamble. Applicants have amended claim 5 to include that the computer-readable medium containing instructions for a method. As such, Applicants submit that amended claim 15 is not indefinite and request withdrawal of the §112 rejection of claim 15.

CONCLUSION

For at least the reasons stated above, claims 1, 3, 5-8, 10, 12-15, 17 and 19-21 are believed to be in condition for allowance and such favorable action is respectfully requested. As such, Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action.

The fee for a three-month extension of time is submitted herewith. It is believed that no additional fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.114071.

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Respectfully submitted,

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